

**Conference Call Summary Statement**  
**RE: Draft FACDQ Meeting #4 Summary**  
**Day 2 – Thursday, March 30, 2006, 8:00 AM – 4:00 PM**  
**Discussion of Measurement Quality Objectives**  
**September 14, 2006**

On Thursday, September 14, 2006, four members of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs – John Phillips, Nan Thomey, Jim Pletl and Tim Fitzpatrick – met via conference call with Triangle Associates, committee facilitator. The purpose of the call was to review proposed revisions to the draft summary of the committee's March 2006 discussions of False Negative Rate measurement quality objectives (MQOs) so that the summary accurately reflected what had been said and agreed to about the False Negative Rate MQO at that meeting.

In advance of the call, Triangle Associates distributed to the call participants a transcript of the MQO discussion from the March meeting along with proposed revisions to the draft summary.

After reviewing the transcript, the group agreed that the transcript clearly identified the motion before the committee and showed that the committee had reached consensus on the motion. The motion in the transcript read:

“... if the FACA committee decides at some time in the future that data would be reported below  $L_Q$ , then data reported between  $L_C$  and  $L_Q$  would be reported as detected but not quantified, for example.”

The review group recommended that the action box in the meeting summary reflect the language in the motion. The group also recommended excluding from the committee's action the following statements that were not associated with the motion in the transcript:

“For purposes of pilot testing, numerical data could be used in the calculations. Associated with that value would be a lower bound of  $L_C$  and an upper bound of  $L_Q$  with some probability. A number with a flag would not be reported.”

They agreed that the meeting summary should include these points in the lead-in to the official committee action because the committee had discussed the statements.

The review group acknowledged that the committee would revisit the setting of MQOs for Clean Water Act programs in its final recommendations. The group also recommended that the committee discuss at a future meeting the process for how data would be reported below  $L_Q$  for each use as well as the ramifications and/or importance of using  $L_D$ .

The review group then recommended, by consensus, that the committee adopt Draft Meeting Summary #4 with the changes shown in the attached document.

## **DAY 2 – Thursday, March 30, 2006, 8:00 AM – 4:00 PM**

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Richard Reding, EPA Designated Federal Officer, opened the meeting at 8:00 a.m., welcomed participants to the second day, and turned the meeting over to Alice Shorett, facilitator.

Ms. Shorett thanked everyone for the tremendous amount of work completed the prior evening. She noted that members discussed measurement quality objectives and uses in caucus groups. Technical Work Group members had then worked until 11:00 p.m. to finalize details of the draft pilot study design to present to the full committee.

### **Discussion of Measurement Quality Objectives**

After briefly reviewing the agenda for Day 2, Ms. Shorett distributed a summary of the prior evening's caucus discussions showing each caucus' preferences for measurement quality objectives for false positives, false negatives, precision and accuracy. In addition, she summarized responses from each caucus to the following questions:

1. Do you agree that there should be a single set of MQOs for all uses? If so, why? If not, why not? Should the MQO's be goals for the pilot study and/or goals for the final recommendation?

On this question, Ms. Shorett noted that there was general agreement that there should be a single set of measurement quality objectives for all uses, primarily for simplicity's sake, and that these goals should be set for both the pilot study and the committee's final recommendations.

- Labs: Yes. It is too complicated to use multiple sets of MQOs, which would result in different detection and quantitation limits depending on the use. They should be set for both.
  - Environmental Community: Yes for simplicity. Initially, they should be set for the pilot, but considered for the final recommendation.
  - EPA: Yes because of uniformity and simplicity. These goals would be for the pilot study.
  - States: Yes.
  - Industry: Yes for both.
  - Public Utilities: Yes for both. Certainty is just as important for permit limit determinations as it is for compliance determination. Verification is a key component for MQOs.
2. What use or uses do you want to consider in setting MQOs?
    - Industry: compliance/enforcement
    - Public Utilities: compliance/enforcement
  3. Which MQOs do you prefer for alpha, beta, accuracy and precision? Why (in each case)?

Each of the four measurement quality objectives are discussed below.

4. What flexibility do you have on your position on MQOs? Are there combinations of these four that you could live with?
  - Labs: This is open for discussion.
  - Environmental Community: There is potentially some flexibility; the caucus recognizes the challenge in verifying small alphas and betas.
  - Industry: There is some flexibility on this option; want to demonstrate compliance so there cannot be too high an Alpha-False Positive error rate at  $L_C$  and Beta-False Negative Error Rate at  $L_C$ .
  - Public Utilities: Potentially some on everything except for verification, which is a “must-have” for the caucus.
  - EPA: The caucus has some flexibility.
  - States: Have flexibility on Beta-False Negative Error Rate at  $L_C$ . For compliance, that would not be an issue for the states. The caucus wants achievable detection and quantitation measurement quality objectives.
5. If there is time remaining, please answer: How do you verify that a procedure meets specific MQOs?

On this question, Ms. Shorett said that the general consensus of the six caucuses was that procedures would be verified by analyzing a substantial number of blanks and spikes at the appropriate levels.

- Labs: Analyze a substantial number of blanks and spikes at MQL over time. See if the MQOs are met.
- Environmental Community: Analyze blanks and spikes at appropriate levels.
- EPA: New rule should require this and what should be done if it is not met.
- Industry: Analyze spikes and blanks.
- Public Utilities: For detection, Alpha (% False Positive) error rate at  $L_C$ , use batch blanks; for Beta (% False Negative) error rate at  $L_C$ , use spike blanks; Accuracy – at what level you are interested in ( $L_Q$  and below).

The committee had a significant discussion on the issue of verification. Many committee members had questions of clarification or comments as to how verification would be conducted (e.g., batch-by-batch analysis) and the costs associated with verification.

There was clarification that the committee seems to be using the terms “confirmation” and “verification” interchangeably. In terms of the pilot, facilitator Bob Wheeler said the discussion had focused on how to confirm that procedures met the set measurement quality objectives. In terms of final recommendations, the committee said it wanted to verify that the procedure performed as intended.

Furthermore, the committee agreed to set measurement quality objectives for the pilot study with the understanding that the committee would make decisions at a later date regarding measurement quality objectives for Clean Water Act programs in its final recommendation.

### Measurement Quality Objectives (Question #3)

The committee discussed each of the four measurement quality objectives. In beginning the discussion, the committee reviewed a summary chart that describes the caucus positions (refer to Attachment A) for four (4) parameters:

#### False Positive Rate

The committee started the discussion already near agreement on a false positive rate. The focus of the discussion was the difference between setting a false positive rate at some percentage and not setting one (i.e., 0%). After a brief discussion among the caucuses, the committee agreed to set the false positive rate at less than or equal to 1% for purposes of pilot testing.

**Action:** The committee agreed, for purposes of pilot testing, and by consensus, to set the false positive rate equal to or less than 1%.

**Vote:** 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

#### False Negative Rate

The discussion regarding setting a false negative rate included:

- Consideration of whether or not the absence of  $L_D$  in the single-laboratory pilot study impacted this decision,
- How data would be reported between  $L_C$  and  $L_Q$  for purposes of pilot testing,
- How that data would be used, and
- How to verify that the measurement quality objective was met.

The committee had considerable discussion on reporting data between  $L_C$  and  $L_Q$ .

Some caucuses added caveats and comments to the proposed action.

- The state caucus noted that “DNQ” was only one of many conventions for reporting results between  $L_C$  and  $L_Q$ , and the caucus was not recommending any specific reporting convention.
- The Public Utility caucus supported reporting data with its uncertainty, but said that implementation of this approach was still an issue.
- The industry caucus expressed concern with reporting any data below  $L_Q$ .
- The laboratory caucus proposed that reporting numbers below  $L_Q$  could be avoided so that some level of accuracy is not implied for a relatively meaningless number by reporting DNQ for values in the range between  $L_C$  and  $L_Q$ . Flags associated with numbers can be lost and reported results used in a way not originally intended. Knowing that results were detected but not quantified informs the user that those results would likely fall in a relatively narrow range between  $L_C$  and  $L_Q$ , which for informational purposes, was as good as an actual value.
- EPA said that by voting in favor of the proposal, committee members were committing to circulating the decision among their constituencies for comment.

Additionally, for purposes of pilot testing, the committee suggested that numerical data could be used in the calculations. Associated with that value would be a lower bound of  $L_C$  and an upper bound of  $L_Q$  with some probability. A number with a flag would not be reported.

The committee voted on and agreed by consensus to the following action.

**Action:** The committee agreed, by consensus, that if or when data is reported below  $L_Q$ , then the data points that fall between  $L_C$  and  $L_Q$  would be reported, for example, as detected but not quantified (e.g. DNQ).

*Vote:* 19 Agree, 0 Not Opposed, 0 Opposed, 2 Absent

After this decision, the committee discussed whether or not to include  $L_D$  for purposes of the single-laboratory pilot testing. Many caucuses agreed that eliminating  $L_D$  for purposes of single-laboratory pilot testing would have little effect. Some committee members made it clear that some procedures would need to be modified to be evaluated in the single-laboratory pilot test.

**Action:** The committee agreed, by consensus, that determination of  $L_D$  was not a requirement for purposes of pilot testing, so long as data between  $L_C$  and  $L_Q$  is reported, for example, as detected but not quantified.

*Vote:* 19 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Finally, the committee addressed setting a measurement quality objective for the false negative rate. The committee clarified in its discussion the need to set measurement quality objectives for purposes of pilot testing with the understanding that once the committee received the data, it might need to re-evaluate where each of the objectives was set. The committee agreed that policy discussions of uses and what each caucus needed in procedures should continue in parallel with the pilot study.

The committee also discussed and agreed to set fixed targets rather than general goals for laboratories to meet. After further discussion, a target for a false negative rate was proposed and voted on.

**Action:** The committee agreed, by consensus, to set the false negative rate equal to or less than 1% measured at  $L_C$  for the true value at  $L_Q$  or  $L_D$  for purposes of pilot testing.

*Straw vote:* 12 Agree, 8 Not Opposed, 0 Opposed, 1 Absent

### Precision

Committee members discussed the practicality of having numbers for precision *and* accuracy versus precision *or* accuracy. Some committee members expressed concern at setting a limit for precision that could potentially make previously-set WQBELs unattainable.

After noting that the committee may re-evaluate limits for its final recommendations based on the pilot test results, the committee agreed to set the precision limit at 20% for the pilot test.

**Action:** The committee agreed, by consensus, that the goal for the pilot test of 20% relative standard deviation (RSD) is based on the mean recovery, understanding that there will be instances where this %RSD may show conflicts with accuracy (that is, set precision targets may inherently define accuracy targets). This may not be applied universally after the pilot study is complete. The study design team will consider higher precision targets (higher %RSD) if the goal cannot be met.

*Vote:* 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

#### Accuracy

Committee members discussed the different ways to define accuracy and decided on an approach for the pilot study.

**Action:** The committee agreed, by consensus, that, for the pilot, the study design team will ask participating laboratories to use accuracy based on mean accuracy and that the Technical Work Group study design team should make decisions on specific goals for accuracy based on an evaluation of existing data. The study design team will ensure that the batch-by-batch data is available for the FACDQ to have analyzed.

*Vote:* 16 Agree, 3 Not Opposed, 0 Opposed, 2 Absent